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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,645	01/24/2002	Anne Gillian Welch	9013.31	8639
20792 7590 04/30/2007 MYERS BIGEL SIBLEY & SAJOVEC PO BOX 37428 RALEIGH, NC 27627			EXAMINER BOESEN, AGNIESZKA	
			ART UNIT	PAPER NUMBER
			1648	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/30/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/889,645	<b>Applicant(s)</b> WELCH ET AL.	
	<b>Examiner</b> Agnieszka Boesen	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 6-19, 23 and 25-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 6-19, 23, 25-27, 29, 30 and 32 is/are rejected.
- 7) ☒ Claim(s) 23, 28 and 31 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

The Amendment filed February 13, 2007 is acknowledged and entered. Claim 1 has been amended. Claims 30-32 have been added. Claims 1, 3, 6-19, 23, and 25-32 are under examination.

#### *Claim Objections*

Claims 23, 28 and 31 are objected to because the claims depend from rejected claim 1.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Rejection of claims 1, 17, 18, 26, and 27 are under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement **is withdrawn** in view of Applicants arguments and submitted product data sheet for the filter.

Rejection of claims 1, 17, 18, 26, and 27 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement **is maintained** for reasons of record (see Office action of July 5, 2006). It appears that Applicant failed to address the rejection in the Remarks of February 13, 2007.

#### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Rejection of claims 1, 3, 6-19, 25-27, 29 and new claims 30 and 32 under 35

U.S.C. 103(a) as being unpatentable over Ostreicher et al. (GB 2 045 828 A, 1980) in view of Nebe (WO 96/05846, IDS Paper No. 1) as evidenced by Encyclopedia Britannica ([britannica.com/eb/article-9030299/diatomaceous-earth](http://britannica.com/eb/article-9030299/diatomaceous-earth), access 10/5/2006) **is maintained.**

Applicant's arguments have been fully considered but are not persuasive. Applicants argue that because at the time of the present invention, there was a very limited knowledge about the structures of abnormal versus normal prion proteins, and the prion proteins were not characterized as "submicron contaminants", one of ordinary skill in the art would not have known whether prion proteins could be effectively removed by filtration and what type of filter and/or filter pore size should have been used. Examiner respectfully disagrees. It is noted that Nebe teaches that prion proteins can be removed using filters that provide retention from 2.0 microns to 0.2 microns (see page 10). Nebe also teaches that using filters providing retention from 2.0 microns to 0.2 microns removes prion protein by factor of  $10^{4.67}$  (see page 14). The present claims require that the pore size of the kieselguhr and perlite should provide retention less than 6 microns. Nebe has successfully filtered prion particles using filters providing retention less than 6 microns, particularly filter providing retention 2.0 microns to 0.2 microns was most effective. Because Nebe knew that for successful removal of prion protein, the filter should have had the capacity to remove particles that had a size of 0.2 microns, thus Nebe must have known that the particle size of the prion protein was under 1 micron. Thus at the time of the

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present invention it has been known that the size of a prion protein was at least 0.2 microns or larger. Therefore at the time of the present invention it has been known that prion proteins were "submicron contaminants". Because Ostreicher teaches a method of removal of submicron contaminants such as bacteria and viruses from aqueous liquids such as biological liquids using a filter formed of self-bonding matrix (binder) comprising cellulose, diatomaceous earth and perlite particles and Nebe teaches that prion proteins can be removed using filters that provide retention from 2.0 microns to 0.2 microns one would have been motivated to use Ostreicher's filter to remove Nebe's prion proteins from biological liquids. With regard to the new claim 32 drawn to the specific permeability of the filter it is considered that choosing the filter with particular permeability in the present method is a matter of optimization of the filtration. Absent the unexpected results the limitation, drawn to the specific permeability, is determined to be obvious to one of ordinary skill in the art.

Applicant filed a Declaration of Dr. Ian MacGrevor under 37 C.F.R § 1.132 on February 13, 2007. Applicant submits that declaration compares the difference in properties of normal and abnormal prion proteins derived from their three-dimensional structure. Applicant argues that because the particle size of prion proteins was not characterized at the time of the present invention, one of ordinary skill in the art would not have known that filtration would be an effective method of removing abnormal prion proteins and what filter pore size should have been used. It is noted that the Declaration of Dr. Ian MacGrevor does not refer to the present application but it refers to application 10/518,471 and a reference by James et al. cited in an Office action in application 10/518,471. Because points 2, 4, 6 and 7 of the Declaration are not relevant in the present application those parts of the Declaration are not considered in the present

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Office action. Applicant particularly points out to section 5 of the Declaration as providing evidence that particle size of prion proteins was not characterized at the time of the current invention.

- In point 5 of the Declaration, Dr. Ian MacGregor states that infectious prion proteins are often found in fibrils in contrast to the normal prion proteins that mainly exist as monomer or sometimes dimer.

In response to the Declaration of Dr. Ian MacGregor the Office acknowledges that differences exist between normal and pathogenic prion proteins. However, as it is evidenced by Nebe, that the infectious prion proteins can be removed from a sample using filter with retention pore size of 2.0 to 0.2 microns, it is herein determined that at the time of the current invention the ordinary artisan knew that prion particles were as small as 0.2 microns. It is expected that the infectious prion proteins that are found in fibrils will be even larger than monomer prion particles and thus the infectious prion proteins in fibril form will be retained on filter that has retention pore size of 0.2 micron. For the reasons discussed above the current rejection is maintained.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*AB*

Agnieszka Boesen, Ph.D.

*4/26/07*

*Stacy B. Chen 4/26/07*  
STACY B. CHEN  
PRIMARY EXAMINER